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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,842	11/14/2001	James Hunter Boone	TLAB.79219	3654

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,842	BOONE ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice of Informal or Non-responsive Amendment

1. Applicants have submitted corrected amendments to obviate the notice of informal or non-responsive amendment dated 2/23/04 and 5/7/04 (paper filed 5/6/04).

Amendment Entry

2. Applicant's response and amendment to the office action mailed November 18, 2003 is acknowledged (Paper filed 2/23/04). In the amendment filed therein claims 1, 4, 6, 7, 8, 9, and 12-14 have been modified. Currently claims 1-9 and 12-16 are pending and under consideration.

3. Objections and/or rejections of record not reiterated below have been withdrawn.

Applicant has not addressed the following objection regarding the IDS therefore it is maintained.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

5. The information disclosure statement filed 4/26/03 in paper #6 has been considered as to the merits before First Action.

AC

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996).

Sugi et al. disclose that lactoferrin (LF) levels were elevated in fecal samples of patients with inflammatory bowel disease. The extracellular (endogenous) release of LF was the most efficient and stable inflammation maker found in feces. See abstract. LF was taught to be a superior maker for intestinal inflammation.

Specifically, LF was elevated in inflammatory bowel disease like active ulcerated colitis - UC and Crohn's disease - CD patients when compared to control subjects. See page 930, Table 1 and page 932, 1st column.

Mucosal measurements of LF in patients with inflammatory bowel disease (IBD) were also conducted to further characterize Lf as a marker (claim 4). See page 931 Discussion.

Lactoferrin concentrations were detected via an ELISA assay. The samples were diluted from 100- to 10,000 fold in 0.1M Tris-HCl buffer before testing (claims 2 and 3). A color (qualitative) reaction was measured at 510/630nm (claim 5). See page 928 2nd column 3rd paragraph.

Sugi et al. teach elevation of lactoferrin in inflammatory diseases. Although, Sugi et al. are silent with respect to non-inflammatory diseases, this is an obvious modification of the method determining wherein elevated lactoferrin is indicative of inflammatory disorders, thus this same elevation would preclude the diagnoses of non-inflammatory etiologies such as irritable bowel syndrome (IBS).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to preclude the determination of non-inflammatory diseases like IBS with the detection of elevated LF in the test sample, because Sugi teaches LF association with inflammatory disease, therefore one could conclude that if LF is elevated then IBS and other non-inflammatory etiologies would be ruled out.

II. Claims 6-9 and 12-16 are rejected under 35 U.S.C.103(a) as being unpatentable over Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996) of Peen et al. (Gut, 1993, 34, 56-62).

Please see Sugi et al. as set forth above.

Sugi et al. differ from the instant invention in not specifically teaching the utility of polyclonal antibodies at an optical density measurement of 450nm and greater that .200 in their assay procedures.

However, Pene et al. teach ELISA procedures measuring lactloferrin with these parameters. See page 57 –58. Pene et al. employed polyclonal rabbit anti-human lactoferrin from Sweden (claim 6). See page 58 Rabbit Anti-Lactoferrin Antisera. In the assay, plates were coated with the antigen and samples (antibody bound sample).

The bound complex was then exposed to alkaline-phosphatase conjugated rabbit human antibodies (enzyme linked antibody). The enzyme linked antibody bound sample complex was measured at 405nm at 1.0 (greater than 0.2). See page 57, 2nd column ELISA.

With respect to the optical density measurement being 450nm, this is deemed routine adjustment for optimizing the assays taught by Sugi et al. in view of Pene et al. Absent evidence to the contrary this detection parameter is routine optimization. This routine optimization position is supported by the instant disclosure on page 11 lines 14-20.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to measure lactoferrin with polyclonal antibodies, at an optical density measurements at 450nm, greater that .200 as taught by Peen et al. in the method of Sugi et al. because Peen et al. taught that their method was quick and accurate. See Figure 1 and page 59 2nd column.

Response to Arguments

Applicant's arguments against the references of Guerrant et al. and Peen et al. (1996) are MOOT because the references have been withdrawn.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Applicant argues that claim 1 is directed to a method for precluding a diagnosis of IBS and other non-inflammatory diseases by determining that a fecal sample does not contain LF – See page 8 and 9) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 1 recites that if the sample does contain elevated LF than IBS and other non-inflammatory diseases are precluded

Applicant contends that the references do not teach or suggest the preclusion of non-inflammatory etiologies. Although the references teach the measurement of elevated lactoferrin in inflammatory diseases, they are silent with respect to non-inflammatory disorders . This argument was carefully considered but not found persuasive because Sugi et al. disclose the measurement of elevated lactoferrin as a marker for inflammatory disorders.

Therefore the maker for inflammatory diseases would obviously preclude (rule out in advance) the detection of non-inflammatory events. A reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. *In re Boe,* 355 F.2d 961, 148 USPQ 507 (CCPA 1966). *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966). Also Sugi et al. teach the measurement of the same maker (lactoferrin), which is capable of performing the claimed function (preclude non-inflammatory etiologies). Performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison,* 69 USPQ 138.

Applicant contends that the reference of Peen et. al. (1993) teaches the detection of lactoferrin in serum samples not in fecal samples. This argument was carefully considered but not found persuasive because the Peen et al. reference was not relied on for teaching fecal lactoferrin measurement. Sugi et al. are cited in combination with Peen et al. and Sugi et al. disclose fecal lactoferrin measurements.

While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F.2d 1005, 150 USPQ 741, 746 (CCPA 1966). Both Sugi et al. and Peen (1993) disclose elevated lactoferrin in inflammatory disorders and therefore they necessarily preclude the measurement on non-inflammatory disease.

Applicant argues that Sugi et al. measure color development at 510/630nm and Peen et al. (1993) measure the enzyme bound antibody sample at 405nm. While the claims require detection at 450nm to determine lactoferrin elevation in fecal samples.

This argument was carefully considered but not found persuasive because the specification teaches optical density detection as an adjustable parameter in order to optimize the assay. See page 11 lines 14-20. Applicant has not shown evidence of unexpected results with the 450nm detection over the wavelength measurements taught by Sugi et al. and Peen et al. (1993). It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33 (CCPA 1937). *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

8. For reasons aforementioned, no claims are allowed.

Remarks

9. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Pool et al. (Gut, 1993, 34, 46-50) teach ELISA techniques to measure autoantibodies involved in inflammatory bowel disease.

B. Guerrant et al. (US Patent #5,124,252) teach in vitro fecal tests to measure lactoferrin.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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03/07/05